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A Warning Detector for Urinary Incontinence for Home Health Care

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A telemetry system for monitoring urinary incontinence has been developed using two principles, temperature and impedance changes of a diaper. The system is composed of a pair of sensors, a transmitter, and a receiver. Temperature changes are monitored using thermistors, one in the center of the diaper and the other attached to the abdomen, and the temperature differences between them after urinary incontinence is detected. For the impedance method, two electroconductive cloths as electrodes placed in the diaper are used as sensors. Urine acts as a conductor to produce a current between the

sensors. Clinical evaluation showed that both methods operate well; 13 of 17 incontinence episodes were detected using the temperature method and 32 of 35 with the impedance method. The misdetections were caused by faulty sensor arrangement for temperature measurement and by detection of exudates by the conductive sensors. These monitors may be used for the care of elderly people who use diapers for home health care, to save care time and help maintain hygiene. (BIOMEDICAL INSTRUMENTATION & TECHNOLOGY 1995;29:343-349)

Various monitors and devices have been developed to assist helpers and nurses involved in the home health care of elderly people. Such monitors and devices should be highly reliable, simple to operate, and inexpensive. The system proposed here has been designed to detect urinary incontinence, early detection of which enables elderly people to keep clean and helps to prevent pressure sores from developing.

Urinary incontinence has been studied in a urodynamic investigation. Clinically, the volume of urine is measured to obtain a quantitative evaluation and to assess treatments for urinary incontinence. Electrical napkins¹⁻³ have been developed for continuous detection of the amounts of urine lost. These napkins are equipped with band electrodes, between which capacitance is measured and related to the amounts of urine the nap-

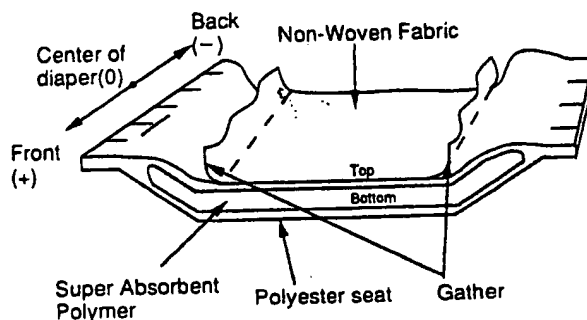


Figure 1. Structure of the disposable diaper used for the temperature-measurement system.

kins have absorbed. The band electrodes are inserted into the diaper, and the monitor is carried over the shoulder. This monitor can be used as a simple detector, but it is too large to handle for home health care, for which a simple, easily portable detector is required.

The criteria for home-care urinary-incontinence-monitoring systems are as follows:

1. Inexpensive sensors should be used so both the diapers and the sensors are disposable.
2. The sensors should be attached to a disposable diaper, so that helpers and nurses can take care of elderly people easily. Complicated monitoring processes must be avoided for the home health monitor.

Received from the Institute for Medical and Dental Engineering, Tokyo Medical and Dental University, 2-3-10, Kanda-Surugadai, Chiyoda, Tokyo 101, Japan (TT, TF); the Department of Electrical and Electronic Engineering, Yamaguchi University, Ube, Yamaguchi, Japan (KN, TM); and Fujimoto Hospital, Miyakonojo, Miyazaki, Japan (SS, MS).

Supported in part by a grant from the Japan Foundation for Aging and Health, 1990-1992, and Suzuken Memorial Foundation, 1992.

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DETECTOR FOR URINARY INCONTINENCE

TAMURA ET AL.

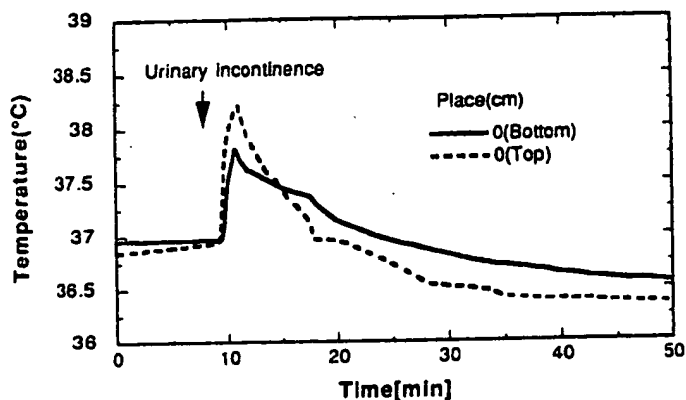


Figure 2. Time course of temperature changes with water spread through the diaper.

3. The incontinence alarm system must warn the caretaker/patient when a sensor becomes disconnected and when the battery is low, to prevent detection failure.

4. The monitor should be noninvasive, harmless, and well tolerated by fragile elderly people.

In order to satisfy these criteria, a simple urinary incontinence detector was developed in our laboratory.

DIAPER CHARACTERISTICS

Before discussing the detection system, the characteristics of the disposable diaper used are considered. The diaper structure is shown in Figure 1. Layers of a non-woven fabric are covered with an absorbent polymer sheet and both materials are covered with a waterproof polymer sheet. A gather along each edge of the diaper helps to prevent leakage of urine. The detecting sensor's position is indicated by a + sign if it is towards the front of the diaper and a - sign if it is towards the back.

First, the temperature changes of the diaper were investigated. In a model experiment, a mannequin was used as a human model. The temperature of the mannequin surface was kept at around body temperature with an electric blanket. Two thermistors were used, one thermistor placed in the center of the diaper and the other 3 cm away towards the back (- direction, Figure 1). Both were mounted on the surface by adhesive tape. A diaper was attached to the mannequin's body and water at approximately 37 °C was dropped onto the diaper. In five trials, the average temperature increases obtained at the center of the diaper and 3 cm from the center were $0.7\text{ }^{\circ}\text{C} \pm 0.3\text{ }^{\circ}\text{C}$ and $0.5\text{ }^{\circ}\text{C} \pm 0.2\text{ }^{\circ}\text{C}$, respectively.

In an ex-vivo study, two thermistors were attached in various places to the diaper surface with lead wires.

Subjects who needed assistance to move were each fitted with a disposable diaper, the temperature of which was recorded continuously and sampled every 10 s. A typical example of the time course of temperature changes is shown in Figure 2. The two thermistors were attached to the non-woven fabric. Before urinary incontinence occurred, the temperatures recorded were those of the diaper, whereas after urinary incontinence, the diaper temperature increased and after one minute, fell exponentially to below the initial diaper temperature. The temperature at the top of the diaper rose by approximately $1.5\text{ }^{\circ}\text{C}$ within 30 s. The average temperature increase was $1.3\text{ }^{\circ}\text{C} \pm 0.5\text{ }^{\circ}\text{C}$ for a total of nine urinary incontinence episodes in three different subjects, and the maximum and minimum increases were 2.8 and $0.5\text{ }^{\circ}\text{C}$, respectively.

Therefore, on the basis of the ex-vivo and model study results, the threshold detection level was found to be $0.5\text{ }^{\circ}\text{C}$.

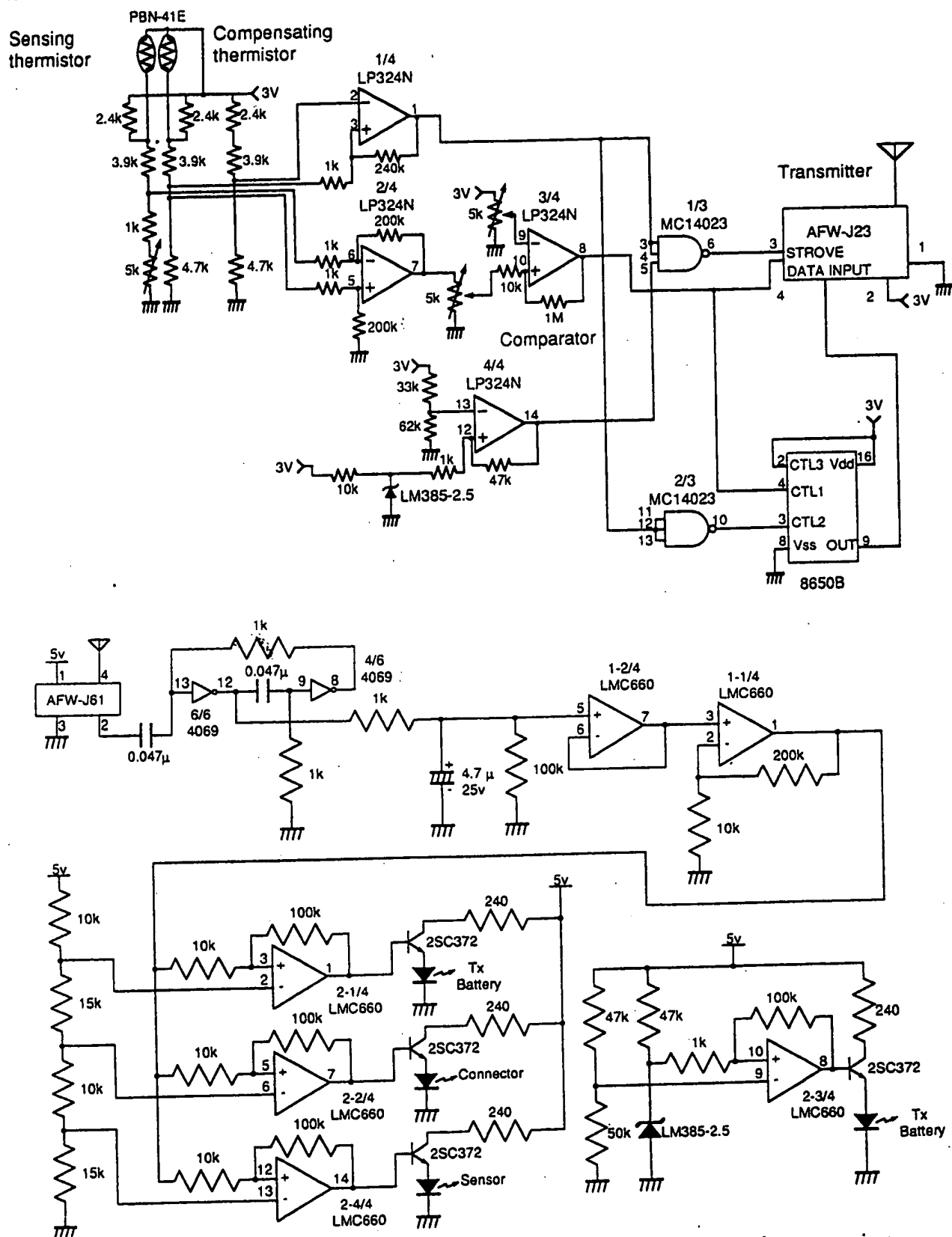
The spread of water through the diaper also was investigated. The relationship between water volume and the water trace was determined using the model study system. Known volumes of water containing black ink were dropped onto the diaper and the spread of the water was observed using video recordings. When all the water had been applied, the wet surface area of the diaper was measured. The water spread over the non-woven fabric surface and then penetrated to the absorbent polymer. The diameter of the wet area increased according to the square root of the water volume. The diameters of wet area were 12.5 ± 1.1 , 16.3 ± 0.7 , 18.6 ± 0.6 , and 21.4 ± 0.5 cm for water volumes of 50, 100, 150, and 200 ml, respectively.

In view of these findings, we decided to place the detection sensor in the center of the disposable diaper and then studied two different parameters, temperature changes and impedance changes of the diaper. The system is designed so that, when an episode of urinary incontinence occurs, the detector operates and warns the family or a helper, who may not always be in the immediate vicinity. Therefore the system consists of a detector, in the form of either temperature or impedance sensors responding to urine flow, a transmitter, and a receiver. Details of the two detecting sensors are given below.

TEMPERATURE MEASUREMENT

Apparatus

The system consists of a pair of sensors (thermistor; PB 43, Shibaura Electric Co., Saitama, Japan), a transmitter, and a receiver. The thermistor, 4.2 mm in length and 2.5 mm in diameter, has a response time of 12 s.



DETECTOR FOR URINARY INCONTINENCE

TAMURA ET AL

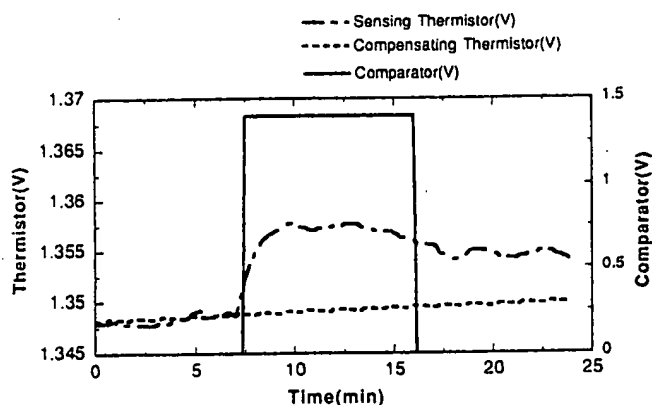


Figure 4. Comparator activation after urinary incontinence.

an operating temperature of -50 to 300°C , a range of resistance of $2.1\text{ k}\Omega$ to $1400\text{ k}\Omega$, and a β value of $3,450\text{ K} \pm 2\%$. Diaper temperature changes in two thermistors were monitored. The thermistors were covered with thick surgical tape to prevent irritation. The circuit diagram is shown in Figure 3. The sensing thermistor was placed approximately in the center of the diaper and the compensating thermistor was placed in an upper part, which was in contact with the abdomen and recorded the skin temperature. The difference between the temperature at the diaper center and that of the abdominal skin after urinary incontinence was recorded. When it reached the threshold of 0.5°C (determined in the ex-vivo and model experiments), the transmitter was activated, the signal detected, and a warning displayed by an alarm light-emitting diode (LED). Bypassing the telemetry system with direct wiring to obtain an analog output, we performed one experiment with an elderly incontinent person to investigate the operation of the temperature sensors and comparator.

Figure 4 is a typical recording of the comparator output. The sensing and compensating thermistors showed similar temperatures before urinary incontinence occurred, whereas afterwards, the temperature in the diaper center increased, and the comparator was activated and sent a signal to the transmitter. When the temperature decreased the comparator switched off but the LED warning light remained switched on. The difference between the activation and inactivation levels of the comparator was the result of its hysteresis.

Additional alarm systems included a battery checker, which operated when the power-supply voltage fell below 3.5 V , and a sensor-disconnection-warning system composed of bridge circuits that operated comparators when disconnection occurred. The three systems were differentiated from each other by transmitting three different frequencies, which were received and detected

to illuminate three LEDs of different colors.

The transmitter and receiver used were commercially available devices (AFW-J23 and AFW-J61, Mitsumi Electric Co, Ltd., Tochigi, Japan, respectively). The frequency used was 309.7 MHz and the maximum propagation distance was 10 m , with a $1/4\lambda$ antenna inside the housing. The transmitter was 60 mm long \times 40 mm wide \times 6 mm high and weighed 38 g , the battery used was a 3-V Mn-Li (CR2032, Hitachi Maxell, Hitachi, Japan), and the levels of current consumption of the system were 6.8 and 1.6 mA during transmitting and resting stages, respectively. The battery life for continuous transmission was 10 h . The transmitter was placed under a diaper cover and connected to the sensor, which made contact with the disposable diaper via a lead.

We have mentioned that the sensing thermistor was placed in the center of the diaper (under the vulva for women and the glans penis for men) and the compensating thermistor was placed near the abdomen. However, when the diapers were put on by helpers and nurses, the sensors often were positioned inaccurately during monitoring.

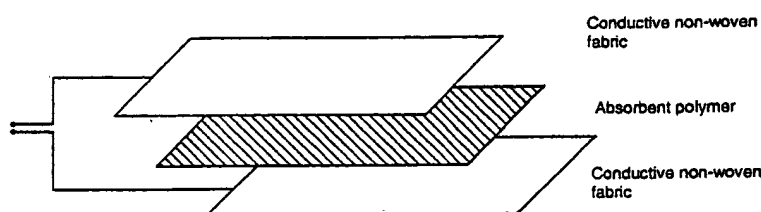
Experiment

For the clinical evaluation, bedfast patients and those who used wheelchairs in Daigo Hospital and the Nakago-en home for aged people, Miyakonojo, Miyazaki, Japan, were monitored. The experiments were carried out between January and March 1993. When the urinary incontinence alarm flashed, the diaper was checked to see whether urination had occurred. The urinary volume during each episode was measured by weighing the diaper.

Table 1. Results of Clinical Evaluation of the Temperature-based Method of Detecting Urinary Incontinence

Urine Volume (ml)	Number of Correct Indicator Signals	Number of Incorrect Indicator Signals
0	1	—
20	2	1
30	2	—
50	2	2
70	—	1
80	1	—
110	1	—
120	1	—
130	1	—
150	2	—
180	1	—

Figure 5. Structure of the disposable diaper used with the electrical-impedance-measurement system.



Results

Table 1 shows the results obtained with the temperature-measurement sensors. Thirteen of 17 urinary incontinence episodes were detected correctly. The minimum volume of urine detected was 20 ml.

The errors of the system were caused by:

1. Incorrect sensor positions. For three of the four episodes that were not detected, the volumes of urine were less than 20 ml and the urine did not reach the sensors. In the other, the sensing thermistor had moved after it was attached to the diaper and the urine failed to reach it. When the sensor moved to more than 15 cm from the center of the diaper, the thermistor could not detect urinary incontinence even when urine volume was 50 ml.

2. Incorrect threshold level. When the difference between the abdominal skin and the diaper center temperatures exceeded 0.5 °C, the alarm signal would flash even though urinary incontinence had not occurred.

IMPEDANCE METHOD

Apparatus

For the impedance method, two electrically conductive cloths, one made of conductive non-woven fabric and the other of commercially available conductive cloth (Thunderon®, Kyoto, Japan) cover absorbent layers of the diaper (Figure 5). The conductive non-woven fabric is attached to an absorbent polymer by double-sided adhesive tape. Before urinary incontinence, the circuit maintains high impedance. When urinary incontinence occurs, a current flows through the cloths, as urine contains electrolytes, and the detecting voltage increases in a stepwise fashion. This voltage is compared with the threshold voltage. When the detecting voltage is higher than the threshold voltage, the transmitter is activated and the receiving system responds.

The circuit diagram of the sensing part of this system is shown in Figure 6.

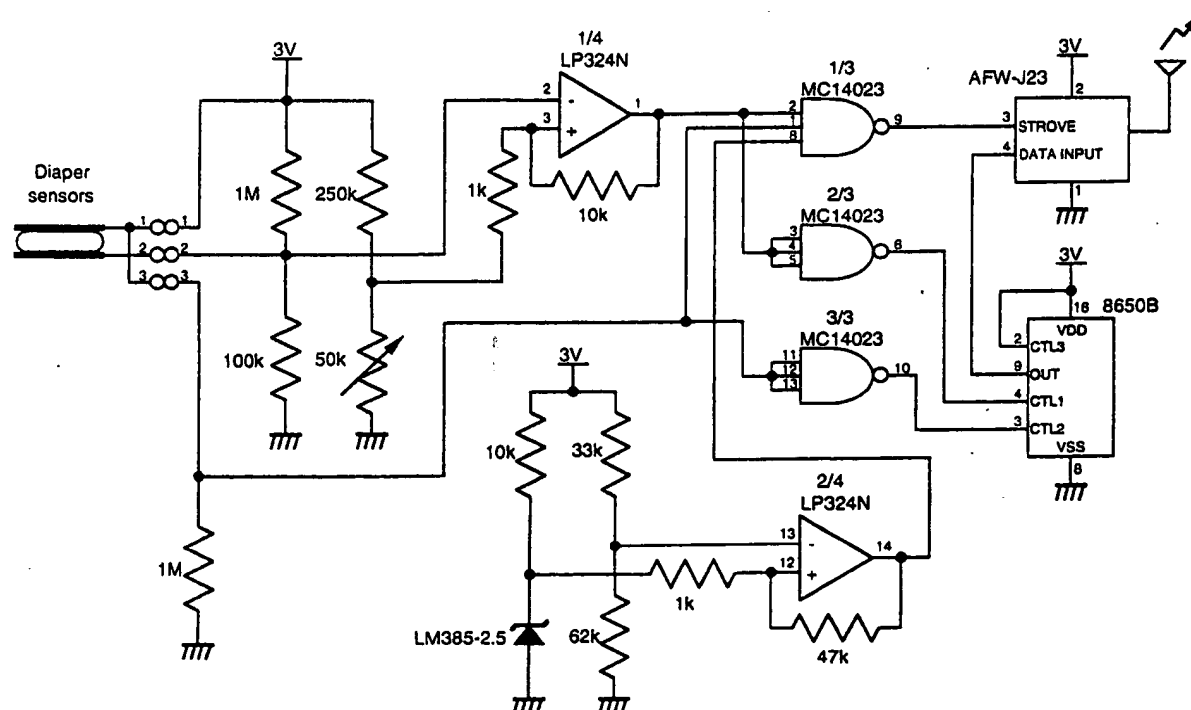


Figure 6. Circuit diagram of the electrical-impedance-measurement system.

DETECTOR FOR URINARY INCONTINENCE

TAMURA ET AL.

Table 2. Results of Clinical Evaluation of the Electrical-impedance Method of Detecting Urinary Incontinence

	Number of Tests	Indicator On	Error	Urine Volume (ml)
Incontinence	30	30	0	151 ± 103
No urination	5	3	3*	

*Resulting from watery stool (one instance) and effusions from bedsores (two instances).

Experiment

The experiment was carried out between March and August 1993, as described above. The effect of humidity was also investigated, because the sweating caused by high humidity in the environment influences the impedance detection.

Results

Table 2 shows the results obtained using the electrical-impedance method. Thirty-two of 35 episodes of urinary incontinence were detected correctly. The subject's posture, such as supine and sitting in a wheelchair or lying on a bed, did not affect detection. Two subjects had no urinary incontinence, but the sensor responded to exudates from pressure sores. The sensor also responded to watery stool for one subject. The minimum detection volume was 20 ml, and the average urine volume was 151 ± 103 ml. The average diaper-wearing time before a detection signal was 2.7 ± 2.1 h; the shortest was 18 min.

DISCUSSION

Urinary incontinence is a common lower urinary tract disorder in elderly people. Urinary incontinence is investigated urodynamically for diagnosing incontinence and assessing treatment efficacy. Urilos² and pad test⁴ experiments have been performed and urine flows per unit time have been measured. Both these pieces of apparatus are used to screen patients, but they cannot be used for home health care, as they are complicated to handle and their designs are research-oriented. In our study, a simple detector system was developed using two different types of sensors.

Both sensors can detect urinary incontinence satisfactorily, and the systems indicate the occurrence of episodes of incontinence without reference to the amount of urine lost. The temperature-measurement method had a false-positive rate that was rather high, but with firmer attachment of the sensors, improvement resulted. De-

tection errors can also be reduced by using an array of sensors.⁵

Least Detectable Volumes. The maximum sensitivity of the thermistor was 1 ml when the urine was released right over the thermistor. However, the positions of the thermistor varied when the diapers were put on by helpers and nurses, and a volume of 50 ml could be sensed even when the sensor moved to 10 cm from the center. Our model experiment also demonstrated that the diameter of the wet area was 12 cm with 50 ml water. The posture of the patient influenced the wet area of the diaper, but the model experiment could roughly estimate the sensitivity of this apparatus according to the urine volume. The impedance sensor could detect a volume of less than 5 ml with an absorbent layer 5 mm thick. The absorbent thicknesses varied with different disposable diapers; urine passing through the layers activates the indicator.

Thermistors can detect quantitative temperature changes and are not affected by patient movement. Without an alarm, this device also can be used to study urinary physiology, such as the duration of urination and the service life of a disposable diaper. Disadvantages of this temperature-detection system are the relatively high cost of the thermistors (\$1 per unit) and high power consumption (19.5 mW). If urinary incontinence occurred four times a day and each alarm lasted about 4 min, battery life would be approximately 50 h, which is quite a high power consumption. An intermittent power supply could improve battery life. Mounting a thin-film thermistor on the disposable diaper center would make it easier to handle than that used in our system.

The impedance method, however, is very simple, uses inexpensive materials, and has low power consumption, although the conductive cloths were sometimes too sensitive and responded to exudates and watery stool as well as to urine. At home, the health care helper and visiting nurse can change the diaper when the alarm flashes. However, in the hospital, helpers and nurses are very busy, and it can be difficult to change diapers frequently. The diaper needs to be changed for ethical and hygienic reasons, when urinary incontinence occurs, but changing a disposable diaper may not be necessary if it is highly absorbent and enables the skin to be kept clean, thus reducing cost. Therefore, an alarm that flashes when the limitation of maximum absorbing volume has been reached is desirable. This device is simple to use and will enable helpers and nurses to change the diapers easily when necessary.

In conclusion, we believe this device will be useful for monitoring urinary incontinence at home. A multi-channel telemetry system will enable it to be used for elderly people in hospitals.

DETECTOR FOR URINARY INCONTINENCE

TAMURA ET AL

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